

**Vendor Audit Survey Form**

(1)

Vendor Audit Survey Form

Date:

5/4/12

Vendor/Company Name: New England Compounding CenterStreet: 6976 Javerly StCity: FraminghamState: MAZip Code: 01702Telephone: 800-594-6322Fax: 508-820-1616**Notice:**

I (we) certify that the information contained in this survey form is accurate and complete as of the date indicated. All information obtained will be kept confidential. This survey has been completed with the permission of the company surveyed.

Bart Fadd  
Signature

President  
Title

Signature

Title

**Part I: GENERAL INFORMATION**Annual Sales: \$ N/AYears in Business: 14Privately Owned: yesSubsidiary Division of: N/AOther Plant Locations: NO

List major Customers:

Type of Contract:

Mass GeneralN/ANY PresbyterianN/AMontefiore HospitalN/ARhode Island HospitalN/A

EXHIBIT

7

(2)

## List Company Management:

Name:

Barry CaddenGregory ConiglioPaul LaguerreRobert Panzio

Title:

Dep/PresidentBMRFOSales Director

Service to be performed for Brigham and Woman's Hospital:

Compounded medications

Total # of Employees:

75

Work Schedule Hours:

8-5 M-F

Number of Shifts:

one

Days per week:

5Are Training Programs for personnel utilized? Yes ☒ No ☐Proficiency Based? Yes ☒ No ☐Certifications Provided? Yes ☒ No ☐

Recertification Period:

Yearly

Describe Training Program:

Comprehensive, mentoring program

(3)

Part II: FACILITY

Number Buildings On-Site: (1)

Type: Single Brick ☒ Multiple Block ☐ Wood Steel ☐

Location: Industrial Park Suburban ☒ Urban ☐ Rural ☐

Equipment: Owned Leased ☒

Square Footage: 30K sq ft

List Process Capabilities and/or Services Provided:

1. all compounded medications
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_

Have you been inspected by any state or Federal Agencies within the last two years?

Yes ☒ No ☐

Name of Agencies:

Title:

Massachusetts board of pharmacy

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Do you have Liability Insurance? Yes ☒ No ☐

(4)

Are written compounding procedures (SOPs) in place? Yes ☒ No ☐How often are procedures reviewed? yearlyAre procedures under change control? Yes ☒ No ☐Describe revision process: yearly or as needed based upon significant process changesHow is training of newly revised documents handled?: must be read & signed off by employees who are impactedAre calibration records kept on file? Yes ☒ No ☐Are calibration standard traceable? 7 Yes ☐ No ☐

Describe: \_\_\_\_\_

**Part III: QUALITY CONTROL/ASSURANCE**Does the Quality Unit report directly to the top management? Yes ☒ No ☐Does the Quality Unit have full authority to reject CSPs? Yes ☒ No ☐Are the Quality Unit procedures in a formal written document? Yes ☒ No ☐Are the procedures revised on a periodic basis? Yes ☒ No ☐Does the Quality Unit have an adequate education, training, and experience? Yes ☒ No ☐Is the facility registered or licensed by a federal, state, or professional agency? Yes ☒ No ☐Which ones: MA board of pharmacyIs there a formal quality assurance program involving Performance testing of equipment used for testing? Yes ☒ No ☐

(5)

**Part IV: CUSTOMER COMPLAINTS**

Is there an organization complaint file?

Yes ☒ No ☐

Does each complaint state:

Nature of complaint

Yes ☒ No ☐

Response to customer

Yes ☒ No ☐

Further corrective/preventative action

Yes ☒ No ☐Complaint file kept for 5 years.

Is there a specific review of complaint files for trends?

Yes ☒ No ☐(quarterly)  
Is the review filed as a written summary?Yes ☒ No ☐

Is there a group or individual assigned to handle customer inquiries and follow up on complaints?

Yes ☒ No ☐

Do you perform "in-house" Audits?

Yes ☒ No ☐

What companies have performed audits on your company in the last year? (Please list a minimum of 3 companies.)

NY Presbyterian**Part V: USP >797> QUALITY COMPLIANCE**Describe gowning for CSP: see S.O.P. - use "sterile" full coveralls- one gowned per day- automated hand wash machine w/ disinfectant mixture...

(6)

Who is responsible for cleaning/sanitization programs? QC manager + Pharmacy cleanroom supervisor.

Rotation of Sanitizers?

Yes ☒ No ☐Frequency of cleaning cleanroom daily - weekly - monthly schedule.

Environmental Monitoring Performed?

Yes ☒ No ☐

Surfaces

Yes ☒ No ☐ Type 

Air

Yes ☒ No ☐ Type 

Personnel

Yes ☒ No ☐ Type 

Number of Cleanrooms

twoFrequency of Environmental Monitoring weekly - monthly

Trending Program

Yes ☒ No ☐

Particle Counts

Yes ☒ No ☐

Cleanroom Certification

Yes ☒ No ☐ Frequency 6 months

CSP Testing USP &lt;71&gt; Sterility

Yes ☒ No ☐

CSP Testing USP &lt;85&gt; Endotoxin

Yes ☒ No ☐

Inhibition Testing Performed

Yes ☐ No ☐

USP Testing Performed By

APL - "Analytical Research Labs"

Outside Audit Performed

Yes ☐ No ☒

CSP Proficiency Technician Testing

Yes ☒ No ☐

Risk Level

High ☒ Medium ☐ Low ☐

Frequency

2 6-months.

USP &lt;797&gt; Compliance Program

Yes ☒ No ☐

Formal Quality Unit

Yes ☒ No ☐